UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,093	10/19/2001	S. Rao Cherukuri	24222-X3	6757

7590 09/30/2005

S RAO CHERUKURI
6900 English Muffin Way Unit A
Frederick, MD 21703

EXAMINER
FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 09/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/982,093	CHERUKURI, S. RAO	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 July 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *8-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of request for extension of time, 132-declaration, remarks and request for reconsideration, all filed 07/22/05. Receipt of change of power of attorney filed 06/14/05 is also acknowledged. Claims 1-24 are pending. Claims 8-24 are withdrawn from consideration. Claims 1-7 are examined and venlafaxine is elected for examination. No claims are amended in the submission of 07/22/05.

Claim Rejections - 35 USC § 103

1. Claims 1-7 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Jerussi et al. (US 6,197,828).

Applicant indicates that attempt was made to formulate the composition of Jerussi into 9 mm size tablets without success and referred to the 132-declaration for a showing of unexpected results. Applicant further argues that Jerussi does not suggest the claimed invention and that there is no motivation or suggestion to make a composition of the nature of the instant invention. And, if there were any suggestion, applicant argues, the Jerussi formulation would not be reasonably expected to provide a controlled release of the active agent.

2. Applicant's arguments filed 07/22/05 have been fully considered but they are not persuasive.

Regarding the controlled release nature of the invention and the argument that Jerussi's formulation cannot be controlled release, it is noted that controlled release is dictated by the matrix composition of the formulation. In the instant case, Jerussi discloses the formulation of the instant claims except that Jerussi is silent in the size/diameter of the caplet. The person of ordinary skill in the art would be able to determine the diameter. And in general, differences in

size would not patentably distinguish the caplet of the prior art over the claimed caplet in the absence of a showing. The generic claim 1 is directed broadly to a formulation in caplet form having a diameter of from about 1 mm to about 7 mm and a length of from about 1 mm to about 7 mm, the composition comprising therapeutically effective amount of a pharmaceutical, at least one compressible material and at least one lubricating agent. No specific pharmaceutical is recited. No specific compressible material is recited. No specific lubricating agent is recited. The declaration, which is not commensurate with the scope of the claimed invention, is addressed below.

The 132-declaration:

The declarant states that the formulation in Table III of Jerussi was not compressible (Experiment 2 of the declaration). The declarant in section 5 states that the formulation in Example 7 of Jerussi, being gelatin capsule dosage form is not expected to produce controlled or extended release dosage form; and that the tablet dosage form of Example 7 of Jerussi could not be compressed into a tablet. At the same time, the declarant in Appendix C, compared dissolution patterns of the claimed formulation and Jerussi.

Since declarant was unable to compress the formulations of Jerussi into tablet form, it is not apparent what formulation is used in the comparison. Secondly, the formulation of Jerussi and the claimed formulation are the same in terms of the pharmaceutical, the lubricating material and the compressible material. Jerussi specifically discloses compressing the powder blend into tablets of desired size and shape (column 27, lines 18-22). For the release patterns to be drastically different, it would mean that the formulations are different especially in the matrix that would determine controlled/extended release. Thirdly, the diameter and the length of the

dosage form are from about 1 mm to about 7 mm. Declarant used a 3 mm tablet as the invention and in so doing tested a specific drug size within the range. No data is provided outside of the limits of about 1 mm to 7 mm. Also, in the attempt to compress the formulation of Jerussi, the declarant used a 9 mm size tablet press, which if successful would be different from the 3 mm tablet used. Although the declarant states that the capsule of Jerussi is not expected to provide a controlled release of the active agent, it is noted that Sherman et al., US 6,274,171 discloses extended/controlled release formulation in capsule form comprising Venlafaxine (see Examples 1-7), Munday et al. in the International Journal of Pharmaceutics, 118 (1995) 251-255 discloses sustained release capsule formulation of theophylline, specifically, here 3 mm tabs are used.

No claim is allowed.

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600